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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,571	07/13/2000	Paul Harris	5951.010-US	4949

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NOVOZYMES BIOTECH, INC.
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DAVIS, CA 95616

EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/28/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/615,571

Applicant(s)

HARRIS ET AL.

Examiner

Scott Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 125-128 is/are allowed.
- 6) ☒ Claim(s) 100-104, 108-111, 113-115 and 117-124 is/are rejected.
- 7) ☒ Claim(s) 105-107, 112 and 116 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed 6/13/02 has been entered. Claims 71-99 have been cancelled. Claims 100-128 have been added. Claims 100-128 are nearly identical to, and correspond to, cancelled claims 71-99, respectively. Only claims 107, 109-111 and 117-119 have changes relative to the previous claims.

The rejection of claim 87 under 35 USC 112, 1st para., replaced by claim 116, has been obviated by the statement under 37 CFR 1.808 filed 6/13/02.

The rejection of claim 78 under 35 USC 112, 1st para. and claims 80-82 and 88-90 under 35 USC 112, 2nd para. is moot in light of new claims 107, 109-111 and 117-119, respectively.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement filed 6/13/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but JP 10155493 referred to therein has not been considered.

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Claim Rejections - 35 USC § 112

Claims 100-104, 108-111, 113-115, and 120-124 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record applied to claims 71-75, 79-82, 84-86, and 91-95, respectively, in the Office action of 12/7/01.

Claims 100-104, 108-111, 113-115, and 117-124 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence encoding a phospholipase B wherein either the nucleic acid sequence comprises nucleotides 568 to 2045 of SEQ ID NO: 1 or the polypeptide comprises amino acids 20-464 of SEQ ID NO: 2, does not reasonably provide enablement for any other embodiments lying outside this scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims for the reasons of record applied to claims 71-75, 79-82, 84-86, and 88-95, respectively, in the Office action of 12/7/01.

Applicant's arguments filed 6/13/02 have been fully considered but they are not persuasive. It is asserted that limiting the claims to SEQ ID NO: 1 or SEQ ID NO: 2 would not adequately protect the inventors. However, it is Applicant's responsibility to provide a specification which adequately describes and enables the claimed invention in a manner

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commensurate in scope with the claims. For the reasons of record, the instant specification fails to do so.

Applicant argues that one or more conservative amino acid changes in SEQ ID NO: 2 could be made without affecting phospholipase B activity. However, Applicant fails to indicate where the specification teaches those conservative changes that could be made. The specification fails to provide guidance as to what amino acids in SEQ ID NO: 2 can be changed, and in what way, or cannot be changed without the loss of phospholipase B activity. The prior art clearly indicates that one cannot predict such changes, and "painstaking" trial and error experimentation would be required.

With respect to obtaining naturally occurring nucleic acid sequences by Southern blot screening, the claims are not limited to naturally occurring isolates, and the vast majority of species readable on the claims would be expected to be unnatural. Furthermore, the specification provides no indication as to what species of organism would likely comprise a nucleic acid sequence readable on the claims. Also, Applicant is reminded that an adequate written description of a nucleic acid sequence requires more than a statement that it is the invention and disclosure of a "potential" method for isolating it, *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997).

It is asserted that this situation is similar to that in *Wands*. However, Applicant fails to indicate how. The situation in *Wands* is quite different; the issue was whether the failure to provide guidance for preparing monoclonal antibodies would have required undue

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experimentation on the part of one of skill in the art. The evidence showed that it did not, because the methodology was well known and established, and that one of skill knew that even though many hybridomas would have to be screened, one would obtain at least one hybridoma which produced the desired antibody. In the instant case, no evidence has been provided that one of skill in the pertinent art is prepared to make the kind of whole-sale modification of a protein or nucleotide sequence encoding same that is permitted by the instant claims, and then screen the resulting nucleic acid sequences for those which encode an active protein.

Applicant's reliance upon *Goffe* is wholly misplaced. This case dealt with the propriety of limiting an invention to working examples of suitable agglomerable materials for formation of a "non-gaseous agglomerable layer". It was found that the art in this area was neither complex nor unpredictable, and would not require undue experimentation to identify suitable agglomerable materials that were not disclosed. In the instant case, the art is highly unpredictable and complicated, and only one example is provided, SEQ ID NO: 1.

Allowable Subject Matter

Claims 125-128 are allowed.

Claims 105-107, 112, and 116 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

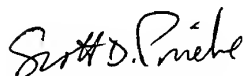
Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). **NOTE:** If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Primary Examiner
Technology Center 1600
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